

ANDERSON EXHIBIT 26N

slightly below the U.S. Consumer Price Index rate for that period. Our price increases for 1991 were also below the CPI, and they are projected to be this year as well.

We appreciate the opportunity to testify and present our views on proposals that are pending before the subcommittee to change the basis for Medicaid rebates. My statement today represents the views of Johnson & Johnson's pharmaceutical companies that market prescription drug products in the United States including Iolab Corporation, Janssen Pharmaceutica, McNeil Consumer Products Company, McNeil Pharmaceutical, Ortho Biotech, and Ortho Pharmaceutical Corporation. Johnson & Johnson's domestic pharmaceutical sales totaled \$1.5 billion last year.

The subcommittee is considering three bills, H.R. 5614 by Representative Slattery, H.R. 2890 by Representative Montgomery, and H.R. 3405 by Representative Wyden. All three attempt to address the problems created by the "best price" basis for Medicaid rebates adopted as part of OBRA in the last Congress. We believe that Congressman Slattery's bill, H.R. 5614, is the right solution.

The recent Congressional Budget Office (CBO) report shows that "best price" provides a declining source of revenues for the Medicaid program. The Medicaid "best price" rebate formula has caused disruption in the marketplace since its inception and has resulted in higher drug prices to a number of purchasers. The only workable solution in our view is to adopt H.R. 5614 with a fixed percentage rebate to replace "best price."

We support Representative Slattery's bill, H.R. 5614, Senator Chafee's bill, S. 2950, and similar legislative proposals to the extent that they accomplish that goal. H.R. 5614 and S. 2950 have a declining fixed percentage rebate which begins at 22 percent and declines to 16 percent in the fourth year and thereafter. Recent projections by CBO indicate these rates are budget neutral, thus raising as much revenue as the current "best price" formula. Adoption of a fixed percentage rebate would help promote and enhance the kind of competitiveness that existed before "best price" and enable companies to continue providing pharmaceutical discounts to a range of volume, public sector, and charitable purchasers.

Johnson & Johnson has a long history of providing substantial financial support to many charitable, health care, and educational institutions. For example, Ortho Pharmaceutical Corporation sells a significant volume of oral contraceptive products to clinics funded under the Public Health Service such as community health centers and family planning clinics at discounts exceeding 90 percent below the average manufacturers price (AMP). We sell other products to these clinics at substantial discounts as well. Programs run by these entities are publicly funded and non-profit in nature.

We have continued to offer substantial discounts to these entities since the Medicaid "best price" rebate program began. However, the "best price" basis for rebates is a disincentive for manufacturers to offer discounts for products unless the discount is greater than 90 percent and is exempt from best price calculations. The disincentive and resulting market disruption arises from the fact that the lowest discount offered to any one purchaser then applies to all its Medicaid volume.

We have encountered a similar situation with the Department of Veterans Affairs (DVA). Historically, we have sold products to the DVA at substantial discounts, as we have to other organizations with a public service orientation. These discounts are also based on the economies of scale which exist with the DVA depot system. However, discounts on the Federal Supply Schedule (FSS), which can be at least 40 to 50 percent or more off the AMP are not commercially reasonable for a larger segment of the market. Even with the advent of "best price" we have continued to provide the DVA with substantial discounts on products, both through the depot and through the FSS, but it is difficult to continue this practice.

We believe the general rise in prescription drug prices you have seen at the DVA would not have occurred if FSS prices had been exempted from "best price" calculations when the Medicaid rebate program was enacted. We support exempting FSS prices from "best price" calculations but we urge the repeal of "best price" as the basis for calculations for the reasons we have just discussed.

Basing Medicaid rebates on "best price" is not equitable. Manufacturers who had offered discounts prior to enactment of OBRA in 1990, and manufacturers who continue to offer discounts to large volume purchasers, to the DVA, and to other non-profit organizations pay significantly higher Medicaid rebates than those manufacturers who did not and do not today offer discounts.

That means that some companies, such as Johnson & Johnson, are paying a disproportionate share of the Medicaid rebates. Johnson & Johnson expects to pay over \$70 million in Medicaid rebates in 1992. This places Johnson & Johnson and other

manufacturers at a competitive disadvantage compared to those who pay only the minimum 12.5 percent rebate.

One would justifiably expect the amount of a rebate paid to the government to be related to total volumes in dollars and/or units but it is not. Under the "best price" formula for 1992 one pharmaceutical company selling a product for \$10 is required to rebate only \$1.25 (the minimum 12.5 percent discount) on the product if they do not offer discounts while another company selling a similar \$10 product is required to rebate \$5 if they offer a 50 percent discount to a single charitable, public, or other purchaser of the product. This is hardly fair and certainly a disincentive for companies to offer such discounts.

As a matter of public policy, a fixed percentage rebate is the only solution that treats all pharmaceutical companies alike and that will maintain incentives for companies to continue their discounts.

Under Congressman Slattery's bill, companies would also be required to provide fixed percentage rebates to the DVA. Senator Chafee's bill would do this and in addition require companies to provide these discounts to qualified Public Health Service-funded clinics. Congressman Wyden's bill, H.R. 3405, extends Medicaid rebates to Public Health Service-supported entities as well but under a "best price" system.

As noted above, we have provided substantial discounts to many community health centers and family planning clinics for many years. In 1991 we voluntarily provided savings to these Public Health Service-funded clinics of nearly \$10 million as compared to our wholesale list price.

One concern we have with extending rebates to all PHS entities is that beyond those organizations with whom we are involved in family planning activities we find it difficult, if not impossible, to identify those entities. Many do not buy products directly from us but use wholesalers. We consequently have no way of determining in many cases which sales ultimately would be eligible for rebates.

Because of this concern we are unable to support proposals for extending additional rebates to these entities at the present time but we would be glad to work with the subcommittee and attempt to explore other alternatives.

We do support providing the DVA with a discount structure comparable to the reasonable fixed percentage rebate proposed in Congressman Slattery's bill, although in our case we already provide them with substantially greater discounts than those proposed in H.R. 5614.

We share the concerns of Congressman Montgomery about pharmaceutical pricing for the DVA. However, we do not support a rollback of DVA prices as would be mandated by H.R. 2890.

Our costs have increased since 1990 and, in a number of areas such as employee costs, at a rate higher than that of the CPI. In addition, we have continued to provide substantial discounts to the DVA program even with the advent of the "best price" formula.

We also have justifiable concern about any mandated price rollbacks because the establishment of price controls would have severe long-term effects upon the viability of the research-based U.S. pharmaceutical industry. The detrimental effects of such measures on drug discovery and development would far outweigh any short-term cost-containment benefits.

Mr. Chairman, we support the legislation proposed by Congressman Slattery and urge you to adopt a fixed percentage rebate for the Medicaid program. On that basis we would support extending these rebates to the DVA program.

A fixed percentage rebate would provide reliable savings for the Medicaid program, help and market disruption and promote the kind of competitiveness that existed before "best price," and stop the inequitable treatment that companies such as ours have endured which "best price" has created.

We would be happy to work with you and your colleagues to achieve this goal.

Mr. WAXMAN. Mr. Ingram.

STATEMENT OF ROBERT A. INGRAM

Mr. INGRAM. Thank you, Mr. Chairman. I am Bob Ingram. I represent GLAXO. Given the hour and the day, I would like to just make two or three points rather than read my oral statement.

We are here to support Congressman Slattery's bill. If OBRA 1990 is referred to, as it is, as the best price system, then Mr. Slattery's bill should be referred to as the best saving system because it will truly provide the best savings for Medicaid, for the Depart-

ment of Veterans Affairs, for hospitals, for HMO's and most importantly, for their patients.

The problem is really very simple. OBRA 1990 created a disincentive for price competition. This fact has been demonstrated and documented by your own Congressional Budget Office and the Department of Veterans Affairs and it has just been testified to today by representatives of the private purchasers.

Mr. Slattery's best savings bill would remove this disincentive and encourage price competition. It will also assure that Medicaid will receive at least the same high level of savings that is expected under the current system and it does so in a more efficient and reliable way.

Mr. Chairman, we recognize that the term "best price" strikes a welcome chord among budget administrators. But that term is illusory. The best price is not the best deal for payers or patients because it does not provide the best savings.

Mr. Chairman, Congressman Slattery's legislation represents sound public policy for the Medicaid system and for the health care system generally.

Thank you.

Mr. WAXMAN. Thank you.

[The prepared statement of Mr. Ingram follows:]

STATEMENT OF ROBERT A. INGRAM, GROUP VICE PRESIDENT, GLAXO INC.

Mr. Chairman, I am Robert A. Ingram, group vice president of Glaxo Inc., a subsidiary of the British-based Glaxo Holdings, p.l.c. Glaxo Inc. is a research-intensive U.S. pharmaceutical company with its headquarters, research and development, and manufacturing facilities located in North Carolina.

I greatly appreciate the opportunity to appear today and offer our full cooperation and assistance in your efforts to control the rising costs of health care.

Glaxo is the second largest manufacturer of ethical pharmaceuticals in the world and the second largest in the U.S. market. As a company committed to intensive medical research, Glaxo invested more than \$1 billion in research and development worldwide last year and will invest even more this year.

We are also a company that appreciates the concerns that have prompted this hearing; namely, how to maintain savings for Medicaid and reduce the costs of prescription drugs for the Department of Veterans Affairs (DVA) and for clinics funded through the Public Health Service.

At Glaxo, we have tried to do our part to address these concerns. For the past 2 years, we at Glaxo have made a commitment to keep our overall average price increases at or below the rate of inflation. We have kept that commitment.

Just this year, we established a program of discounts for certain clinics funded by the Public Health Service. Some of these clinics were already receiving discounts as members of group purchasing organizations. In addition, since 1984, we have had a program through which we make all of our products available free to indigent patients.

Mr. Chairman, we are encouraged by some of the legislation that is being considered by the subcommittee to address these concerns. I hope to convince you that you have the answer to most of your concerns in one bill: H.R. 5614, Congressman Jim Slattery's bill to repeal the "best price" system of Medicaid rebates and implement in its place a budget-neutral system of fixed percentage rebates.

Congressman Slattery's bill would replace the "best price" formula with budget-neutral, fixed percentage rebates in accordance with the study issued by the Congressional Budget Office (CBO) on June 22. The rebates would be 22 percent in fiscal year 1993, 19 percent in 1994, 17 percent in 1995, and 16 percent thereafter. In addition, the bill would require companies to provide discounts to the DVA based on the rebate percentage. DVA, of course, would be free to negotiate even deeper discounts.

As you know, similar legislation has been introduced in the Senate by Senator John Chafee. In addition to replacing the "best price" system with a system of fixed rebates and requiring companies to provide similar discounts to the DVA, Senator Chafee's bill, S. 2950, would require pharmaceutical manufacturers to extend the

same discounts to federally qualified health centers and clinics funded by the Public Health Service. We recommend that H.R. 5614 be amended to provide for guaranteed discounts to these clinics.

As I mentioned, Glaxo is one of a number of companies that have independently offered discounts to these clinics already. We are in full support of that idea and would be glad to cooperate with the committee in developing a system that will provide the most efficient and cost-effective service to these clinics.

While we commend Congressman Wyden for his interest in expanding access to medicines through these clinics, his approach as set forth in H.R. 3405 of including the clinics within the current "best price" rebate system is not the best alternative. It would continue the market disruption currently caused by the "best price" formula, and it would add unnecessary administrative burdens on the clinics, on State Medicaid agencies, and on companies. In addition, with the erosion of "best price" as documented by the CBO, savings for the clinics would be unreliable.

Mr. Chairman, this hearing has been triggered by one compelling realization: the "best price" system for determining rebates is fundamentally flawed. It has undermined competition in the private prescription drug market. And, as the recent report by the CBO demonstrates, it does not even guarantee a stable source of savings for the Medicaid program, which was the principal objective of the Medicaid provisions of OBRA 1990.

The experience of the DVA, which purchases drugs from the Federal Supply Schedule, is a good example of the negative impact that these market disruptions have had. OBRA 1990 did not exclude Federal Supply Schedule prices from the calculation of "best price." According to an analysis done by the DVA, those prices began to increase in the months following enactment of the rebate law. This led to an increase in payments by the DVA.

Mr. Chairman, if Congress were to enact the legislation proposed by Congressman Slaterry and Senator Chafee, the DVA, Medicaid and the private sector would benefit. This legislation would provide a predictable and stable source of savings for the Medicaid program and PHS-funded clinics while still allowing competition in the rest of the market, which in the past has led to cost-savings for the DVA and other high volume purchasers.

In September of 1990, I testified before this subcommittee to discuss Glaxo's proposal to help alleviate some of the financial burdens facing the Medicaid program. At that time, we expressed our concern that a rebate program based on a manufacturer's "best price" for each product would disrupt the pharmaceutical market. Also, we tried to point out how such a system would penalize companies, like Glaxo, that have been willing to engage in price competition and have offered substantial savings for the DVA and other high volume purchasers.

Our experience since enactment of OBRA 1990 has proven that our concerns were justified. In the year preceding the enactment of OBRA 1990, Glaxo gave discounts to the Federal Government that saved the DVA, Department of Defense, and Public Health Service more than \$45 million on our products when you compare their price on the FSS with our net wholesale price. We have historically given high discounts to the DVA, and have continued to do so in 1991.

It is because we have offered such high discounts to the DVA that Glaxo's rebates—in excess of \$100 million—will account for more than one-seventh of the "best price" rebates paid to Medicaid in fiscal year 1992.

Glaxo shares the concern about budget problems facing the Medicaid program. We willingly pay rebates to Medicaid, and in fact Glaxo voluntarily provided rebates to Medicaid prior to the enactment of OBRA 1990. We are here today, Mr. Chairman, because we believe there is a way to provide needed savings to Medicaid without disrupting the marketplace.

While the "best price" system may have seemed like a good idea when the law was enacted, it has become clear that the "best price" formula is disrupting the commercial market, and will fail to provide reliable savings for Medicaid.

You may hear the argument that the Medicaid program deserves the best price available for prescription drugs. But that argument is illusory. Many considerations that support deep discounts in particular market sectors simply do not apply to the Medicaid program.

As a general rule, the purchasers who receive large discounts buy large quantities, take delivery, and pay directly for the product. Medicaid stands in contrast to that. One must keep in mind that Medicaid does not purchase drugs directly; it is a third-party reimbursor. It does not take delivery, and it does not pay directly for prescription drugs.

The real issue for Congress is not whether Medicaid deserves the "best price"; it is how best to save money for Medicaid. A fixed percentage rebate as proposed by Congressman Slattery and Senator Chafee would provide reliable savings and, in doing so, would best serve the Medicaid program.

Additionally, as we have learned during the past year or so, the "best price" approach is complex and cumbersome for both Federal and State Medicaid agencies because prices in the private sector are changing constantly as companies negotiate and renegotiate contracts. We are confident that States and the Federal Government could realize significant savings just by being able to shed the added administrative burdens that have been imposed on them by the "best price" system.

Mr. Chairman, as I said before, enactment of Congressman Slattery's and Senator Chafee's fixed percentage rebate legislation would accomplish the original objectives of the Medicaid provisions of OBRA 1990 without the negative impact that the "best price" system has had on the prescription drug market.

By replacing the "best price" system, these bills would eliminate the pressures that caused DVA prices to increase. Congressman Slattery said it best when he introduced his bill: "With the elimination of the 'best' price from the Medicaid discount formula, large purchasers of pharmaceuticals, including the DVA, would again be able to negotiate discounts with manufacturers based upon the volume of their purchases."

Mr. Chairman, adoption of a fixed percentage rebate would eliminate the need for more drastic measures intended to help the DVA, such as price rollbacks as provided in Congressman Montgomery's bill, H.R. 2890. I should preface my remarks about the proposed rollback by explaining that under the Mikulski amendment and through the DVA depot system, Glaxo has kept its prices to the DVA at or below the pre-OBRA 1990 levels. Because of the mark-up added by the depot, individual DVA hospitals may pay more than when they could buy from us directly at the FSS price; however, as a practical matter, a rollback would have little impact on the prices at which our products are available to the DVA.

Nevertheless, while we appreciate and share Congressman Montgomery's concern over pharmaceutical prices for the DVA, we have grave reservations about any type of price controls or mandated price rollbacks on pharmaceutical products. Such measures have not worked in the past in other segments of the U.S. economy, and they would be unwise now.

In light of the tremendous pressures Congress faces with respect to the Federal budget, if price controls were established for any segment, even a relatively small part of the market like the DVA, there would be a temptation to expand those controls to larger segments of the market in hopes of achieving short term savings.

If that were done, the long-term consequences could be severe. I fear that it would inhibit the discovery and development of new and important medicines by the research-based pharmaceutical industry. Such an emphasis on short term cost containment without regard to its impact on the discovery and development of new drugs will not, in the long-run be cost-effective and will diminish the availability of state-of-the-art medical care for American people.

Currently, U.S. pharmaceutical companies are committing time and resources to search for new, breakthrough therapies because they know they will be able to recover their costs and fund further research if they are successful. Such innovation must be encouraged because it leads to the development of new medicines that drive down the overall cost of medical care and improve the quality of life.

The development of new and better drugs in the future, for example to treat Alzheimer's AID's, cancer, heart disease, etc., will continue to reduce overall medical costs. If, however, price controls are put into place, even the most progressive companies may as a business necessity be tempted to shift their research and development resources to less risky, less costly projects that will not provide the same level of benefit to the country as a whole.

Mr. Chairman, in conclusion, we think you have an excellent opportunity this year to make a very positive change to the Medicaid rebate law. By adopting a fixed percentage rebate, as proposed by Congressman Slattery and Senator Chafee, you can restore price competition to the private market; relieve unnecessary administrative burdens on the Federal Government, State governments, and private companies; and ensure reliable savings to Medicaid, the DVA, and public clinics serving the poor.

Overall, the approach proposed by Congressman Slattery and Senator Chafee would represent a much better public policy for our Medicaid program and for our health care system in general.

If the current system were the only way to realize savings for Medicaid, then it might be worth the market disruption and other problems. But you have a much

better alternative. By adopting this alternative, you will send a message to the marketplace that competition based on economies of scale and free market dynamics is desirable.

I urge you and your colleagues to seize this opportunity.

Mr. WAXMAN. Mr. Mossinghoff.

STATEMENT OF GERALD J. MOSSINGHOFF

Mr. MOSSINGHOFF. Thank you, Mr. Chairman.

As you have heard this afternoon, there is no agreement in the PMA board on the Slattery legislation. But there is unanimous agreement among the board in strong opposition to the price rollback provisions that would be contained in H.R. 2890. That would further distort the U.S. free market system beyond the major market changes already caused by OBRA 1990 that you heard about today.

The bill would require that to participate in the Department of Veterans Affairs procurement manufacturers must agree to supply drugs to DVA through the Federal Supply Schedule and the drug depot at September 1, 1990 prices, adjusted by the inflation factor provided in the President's budget.

Beyond that, manufacturers should not be eligible to participate in the basic Medicaid Drug Rebate Program unless they agree to the price rollback for the Department of Veterans Affairs. That would constitute a far more radical and intrusive disruption of the free market system than was caused by the Medicaid Rebate Program.

The rebate provisions of OBRA 1990 specify the amount of the rebate to be made to the Medicaid program. But H.R. 2890, particularly the price rollback provisions, would actually set the prices at which the DVA would acquire prescription drugs.

The 2-year price rollback required by the legislation is inherently unfair and unprecedented. It would penalize forever those companies that traditionally gave DVA highly discounted prices. In effect, the legislation would reach back in time to pick then existing price levels and apply an index that has no relation at all to the cost of developing or marketing new drugs.

Mr. Chairman, with respect to H.R. 3504 introduced by Congressman Wyden, the PMA board is supportive of providing in some administrable way discounts to the public health facilities and clinics listed in the bill.

We do have concerns about the operation of that bill. The Public Health Service funded community and migrant health centers are listed in the directory published by the Public Health Service. Similarly, a directory of the homeless health care project is published by the National Association of Community Health Centers. The entities listed in subsections A, B, and C of the bill constitute more than 600 centers and more than 2,000 clinics.

We do not have the list of the other "covered entities" nor do we know how many there are. We understand that in some cases the Public Health Service grantees are integral elements of larger health facilities. In other cases, they would be as small as an individual physician's office.

It appears that the covered entities listed in the bill are not reimbursed by the Federal Government for the pharmaceuticals they

purchase and dispense, and that they receive pharmaceuticals through normal commercial distribution systems, including wholesalers and buying groups. Therefore, providing special prices or rebates to them would be totally different administratively and far more complex than providing Medicaid rebates.

In that regard, PMA and our member companies would work with you and Congressman Wyden to see if there is an administratively appropriate way to provide lower prices to those deserving clinics.

Thank you, Mr. Chairman.

[Testimony resumes on p. 217.]

[The prepared statement of Mr. Mossinghoff follows:]

203

Statement

Pharmaceutical
Manufacturers
Association

GERALD J. MOSSINGHOFF
PRESIDENT
PHARMACEUTICAL MANUFACTURERS ASSOCIATION

BEFORE THE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

July 31, 1992

I am Gerald J. Mossinghoff, President of the Pharmaceutical Manufacturers Association. PMA represents more than 100 research-based pharmaceutical companies that discover, develop and produce most of the prescription drugs used in the U.S. and a substantial portion of the medicines used abroad. I appreciate the opportunity to appear today to testify on three bills -- H.R. 2890, H.R. 3405 and H.R. 5614 -- that would either set the prices to be offered, or the rebates to be paid, by pharmaceutical manufacturers for prescription drugs provided to various Government entities.

Under H.R. 2890, pharmaceutical manufacturers, to participate in the Medicaid drug-rebate program established by the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) and in procurement by the Department of Veterans Affairs (DVA), would have to agree to "rollback" their prescription-drug prices to DVA to the level in effect on September 1, 1990, adjusted by the inflation factor of the DVA's Medical Care Account.

1100 Fifteenth Street, N.W. Washington, D.C. 20005 (202) 835-3400

204

2

Under H.R. 3405, pharmaceutical manufacturers would have to provide the same rebates established by OBRA 90 for the Medicaid program to entities receiving funds from the Public Health Service.

H.R. 5614 would replace the OBRA 90 "best-price" formula with a flat-percentage rebate.

PMA strongly opposes H.R. 2890 and H.R. 3405. H.R. 2890 is an unwarranted Government attempt to impose Government price controls on pharmaceuticals. The two-year price rollback is inherently unfair and unprecedented. H.R. 3405 would create more problems than benefits -- and may be impossible to implement. Both bills would further interfere with the U.S. free-market system beyond the major market changes already mandated by OBRA 90. PMA will not take a position on the final bill, H.R. 5614, because the pharmaceutical industry has not reached agreement on the merits of a best-price or flat-percentage rebate for Medicaid.

Price controls, as provided in H.R. 2890, are widely viewed as unworkable, discriminatory and totally contrary to the U.S. free-market system. As applied to the pharmaceutical industry, such controls inevitably would impede the development of new medicines. These views were accepted by the U.S. Senate on March 11, 1992, when, following a thorough eight-hour debate, it

205

3

rejected by a vote of 61 to 36 an amendment that would have imposed a form of tax-enforced price controls on pharmaceuticals.

Before discussing H.R. 2890 and H.R. 3405 in more detail, I would like to outline briefly some of the economic facts of life about the research-based pharmaceutical industry. The industry, according to the March 9, 1992 issue of Fortune magazine, is the country's most internationally competitive industry -- but price-control proposals, such as contained in H.R. 2890, would seriously affect its ability to maintain its competitive edge in world markets.

A HIGHLY COMPETITIVE INDUSTRY

Recent press reports in The New York Times and elsewhere have pointed out that industrial spending on research and development in the U.S. has begun to decline and that Japan threatens to surpass this country in such expenditures, if it has not already done so. The pharmaceutical industry stands out as an exception to the U.S. trend of declining research spending. The pharmaceutical industry continues to increase its huge R&D expenditures -- the key to its success in world markets.

The industry has doubled its investment in research and development every five years since 1970. This year, the industry will spend almost \$11 billion on R&D, 13.5 percent more than last

206

4

year, as shown in Figure 1. Once again, this is more than the entire U.S. Government will spend on all health research.

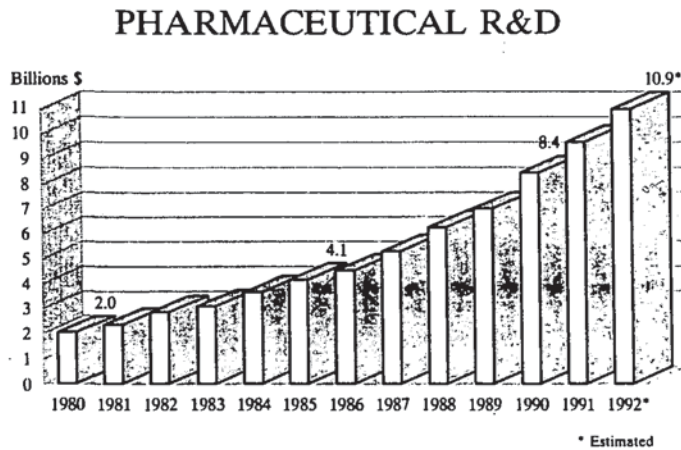


Figure 1.

This year, the industry is investing more than 16 percent of its sales in research and development -- while all U.S. industries engaged in research and development on average invest less than 4 percent of sales in R&D.

Because of its ever-increasing research expenditures, the pharmaceutical industry is the source of nearly all new drugs in

the U.S. and the leading source worldwide. Of the 100 most prescribed patented drugs in the U.S. in 1991, 95 were patented by private industry. Forty-seven of the 97 new drugs marketed worldwide during 1975-1989 originated in the U.S. -- more than three times the number from any other country.

Medicines not only save lives -- they save money. Medicines are the most cost-effective form of medical therapy because they help to reduce the cost of alternative, more expensive forms of medical care, such as surgery and hospitalization.

A recent study by the Battelle Medical Technology and Policy Research Center found that the use of pharmaceuticals saved 1.6 million lives and \$141 billion over the past 50 years for just four diseases -- tuberculosis, polio, coronary heart disease and cerebrovascular disease. Battelle also projected that during the next 25 years the use of pharmaceuticals will save \$68 billion in U.S. health-care costs for Alzheimer's disease while reducing the number of severe cases by almost 400,000. In addition, \$211 billion will be saved in costs for cardiovascular disease with 5 million deaths and 9 million cases avoided. Further, \$180 billion in costs will be saved for arthritis and the number of disabling rheumatoid arthritis cases will be reduced by half and the number of osteoarthritis cases by more than 20 percent.

Despite the progress that has been made in curing disease

and the prospects for future advances, many diseases remain untreated. The research-based pharmaceutical industry provides the best hope for finding new and better treatments. According to a 1991 PMA survey, research-based pharmaceutical companies are involved in developing 329 medicines for diseases that primarily afflict older Americans. The health-care costs of these diseases are staggering. The following table shows the number of drugs in development for seven major diseases that affect the elderly, as well as the estimated cost of each disease and the source of the cost estimate:

UNCURED DISEASES: COSTS AND PROMISING MEDICINES			
<u>Disease</u>	<u>Annual U.S. Cost in Billions</u>	<u>Source of Cost Estimate</u>	<u>New Drugs in Development</u>
Alzheimer's	\$ 88	Alzheimer's Association	13
Arthritis	\$ 35	Arthritis Foundation	22
Cancer	\$ 104	National Cancer Institute	126
Cardiovascular	\$ 95	American Heart Association	93
Depression	\$ 27	Natl. Inst. of Mental Health	16
Diabetes	\$ 20	American Diabetes Association	8
Osteoporosis	\$ 10	National Institute on Aging	21
TOTAL:	\$ 379		299

In all, these seven diseases are estimated to cost \$379 billion a year in the U.S. alone -- an enormous figure that fortunately will be reduced as many of the 299 medicines in development to prevent, cure or treat the seven diseases are approved and marketed. PMA surveys also show that many other medicines are being developed to treat other disabling and costly

209

7

diseases, including 114 drugs and vaccines for pediatric use, 88 medicines and vaccines to treat AIDS and related disorders, 189 orphan drugs, 132 biotechnology medicines and vaccines, and 263 medicines for women.

Because of its success in developing new drugs for world markets, the pharmaceutical industry, unlike most other manufacturing industries, continues to produce more jobs. During the 1980s, almost 2 percent of the jobs in the U.S. manufacturing sector were lost. But the pharmaceutical industry increased its employment by 24 percent during this period, adding 60,000 jobs. PMA companies employ more than 185,000 people in the United States.

The industry also has consistently maintained a positive balance of trade, even in recent years when our country's trade deficit soared. According to the Department of Commerce, the industry's exports have risen from \$2.6 billion in 1984 to an anticipated \$6 billion this year, and our positive trade balance -- \$972 million eight years ago -- is expected to be \$975 million in 1992.

The market share held by the leading pharmaceutical companies highlights the intensely competitive nature of the industry. The sales of the four largest PMA firms account for only 25 percent of total domestic sales. The top eight firms

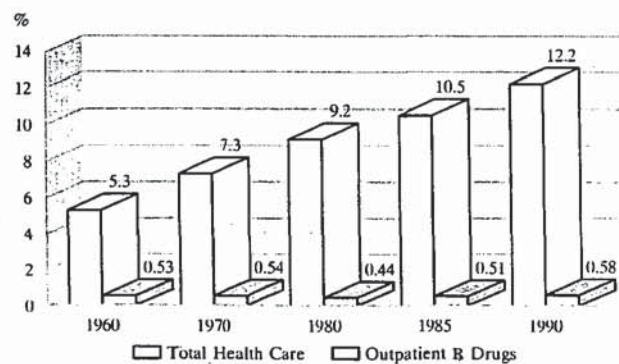
210

8

account for less than 50 percent of the U.S. market. And the sales of 20 companies must be combined to reach 75 percent of the market.

While health-care costs have been increasing rapidly, it is clear that drug expenditures are not the cause of this increase. From 1970 to 1990, health-care spending as a percentage of Gross National Product jumped from 7.3 percent to 12.2 percent. During the same period, spending on outpatient prescription drugs has remained constant -- at about one-half of one percent of GNP for the past 25 years, as shown in Figure 2.

HEALTH CARE EXPENDITURES AS A % OF GNP



Source: Health Care Financing Administration

Figure 2.

211

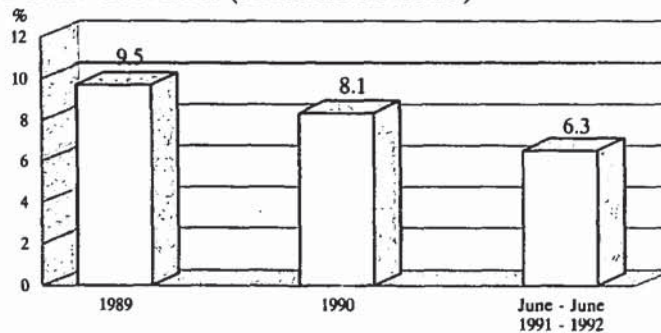
9

In addition, the percentage of U.S. health-care expenditures devoted to pharmaceuticals has actually declined. In 1965, 9 percent of the national health-care budget was spent on outpatient prescription drugs. Currently, less than 5 percent of the health-care budget is spent on outpatient pharmaceuticals -- one nickel out of every health-care dollar.

Further, as shown in Figure 3, pharmaceutical price increases are moderating. Manufacturers' prices, as measured by the Producer Price Index, have dropped from 9.5 percent in 1989 to 6.3 percent in the most recent 12-month period of June 1991 through June 1992.

DRUG PRICES

Producer Price Index (Manufacturers' Prices)



Source: Bureau of Labor Statistics

Figure 3.